

Certificate of Analysis

Product name: Ketoconazolum
Batch number / Weight: 21K18-B06-213373 / 25 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / <=BY4	Conform		
Optical rotation	-0,10 - + 0,10	+0,022	°	
Related substances	Conform	Conform		
Impurity D		0,19	%	
Unspecified impurities		0,06	%	
Total impurities	<=0,5	0,3	%	
Loss on drying	<= 0,5	0,04	%	
Sulphated ash	<= 0,1	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Ketoconazole	99,0 - 101,0	99,73	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

15-04-2022

Expiration: 30-06-2026

Conclusion: APPROVED

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